

Application Number: 10/659,245

Reply To Office Action of MARCH 17, 2005**Amendments to the Claims**

1. (Currently Amended) A needle for delivery of a substance to the skin of a patient, having a skin engaging surface, comprising:  
a shaft having a wall defining a longitudinally extending bore, a first end that is open to receive the substance in the bore, a second end adapted to penetrate skin of a subject, and a penetration length extending from the skin engaging surface to a distal tip of the second end of less than about 4.5 mm; and  
at least one side port extending through the wall and communicating with the bore, the side port being arranged about 0.025 mm to about 3 mm from the skin engaging surface and has a diameter which is adapted for flow at pressures less than 5 psi, wherein when the needle is fully penetrated into the skin, the skin engaging surface contacts the skin, and the substance exits the side port under pressure directly into the skin.
2. (Original) The needle of claim 1, wherein the second end comprises a sharpened tip.
3. (Original) The needle of claim 2, wherein the tip is beveled.
4. (Original) The needle of claim 3, wherein the side port is arranged on a side of the shaft opposite of the bevel.
5. (Original) The needle of claim 1, wherein the second end includes an end port communicating with the bore.
6. (Original) The needle of claim 5, wherein the side port and end port are adapted for bi-phasic delivery of a substance.

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7. (Original) The needle of claim 1, wherein the side port is arranged on the shaft for epidermal delivery of a substance.
8. (Original) The needle of claim 1, wherein the side port is arranged on the shaft for intradermal delivery of a substance.
9. (Previously Presented) The needle of claim 1, wherein the side port is adapted to be about 0.5 mm to about 1.5 mm below a surface of the skin when the needle is inserted into a subject.

Claims 10-39 Canceled

40. (Currently Amended) A drug delivery device for intradermal delivery of a substance into skin comprising:
- a reservoir containing a selected amount of the substance;
  - a needle, having a selected gauge size, a distal end, a proximal end and an axis extending from the distal end to the proximal end, wherein the needle defines a lumen which is in fluid communication with the reservoir, the needle further comprising a tip at the distal end, and the lumen further defining at least one outlet substantially at the distal end at a fixed location with respect to the tip, wherein the outlet is formed by an opening through the side of the needle and has an exposed height in the axial direction that is of a selected length less than the thickness of the intradermal space and the outlet has a diameter which is adapted for flow at pressures within the reservoir of less than 5 psi;
- means for limiting penetration of the needle into the skin such that when the needle is inserted into the skin to the depth determined by the penetration limiting means, and the outlet is at a location entirely within the intradermal space; and

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wherein the gauge size is selected to allow the skin to seal around the needle when in use and leakage of the substance to the surface of the skin is substantially prevented.

41. (Previously Presented) The needle of Claim 40 wherein the outlet is at a depth of about 0.50 mm to 2 mm when the needle is inserted into the skin.
42. (Previously Presented) The needle of Claim 41 wherein the outlet is at a depth of about 0.50 mm to 1.5 mm when the needle is inserted into the skin,
43. (Previously Presented) The needle of Claim 42 which is about 0.30 mm to 2 mm long.
44. (Previously Presented) The needle of Claim 43 which is about 0.50 mm to 1 mm long.
45. (Previously Presented) A device for intradermal delivery of a substance into the skin comprising the needle of Claim 40 and a reservoir in fluid communication with the needle.
46. (Previously Presented) A device as claimed in Claim 45 further optionally comprising pressure-generating means for delivering the substance through the needle.
47. (Previously Presented) A device as claimed in Claim 46 wherein the pressure-generating means provides variable control of substance delivery rate.

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48. (Previously Presented) A needle as claimed in claim 40, wherein the penetration limiting means comprises a hub associated with the shaft of the needle.

49. (Previously Presented) A needle as claimed in claim 40, wherein the outlet is a plurality of outlets.